

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of low-calorie diet alone and in combination with cognitive-behavioural therapy intervention to reduce weight self-stigma on diet adherence and anthropometric indices in adult women with obesity and weight self-stigma: a randomized clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of low-calorie diet alone and combined with cognitive-behavioural therapy intervention on diet adherence and anthropometric indices in adult women with obesity and weight self-stigma

Design

Clinical trial with control group, with parallel groups, non blinded, randomized on 120 samples. The site www.sealedenvelope.com will be used for randomization.

Settings and conduct

The location of the study will be Dr. Keshavarz's nutrition and diet therapy clinic in Tehran. The study population is adult women with obesity and weight self-stigma. This study won't be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study and sign a written consent form; Age between 18 and 50 years; BMI between 30 and 40 Kg/m²; Confirmation of weight self-stigma by questionnaire Exclusion criteria: suffering from certain diseases or a severe condition that affects the study results; Receiving specialized psychological counselling to reduce weight self-stigma in the last three months.

Intervention groups

The intervention group will receive cognitive-behavioral therapy to reduce self-stigma along with the weight loss diet, and the control group will receive the weight-loss diet alone.

Main outcome variables

Weight self-stigma; weight-loss diet adherence; weight; Waist circumference; Hip circumference; Fat mass; Fat free mass; Body water

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140907019082N12**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **retrospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Mahdieh Abbasalizad Farhangi

Name of organization / entity

Department of Community Nutrition School of Nutrition

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-17, 1402/05/26

Expected recruitment end date

2023-10-18, 1402/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of low-calorie diet alone and in combination with cognitive-behavioural therapy intervention to reduce weight self-stigma on diet adherence and anthropometric indices in adult women with obesity and weight self-stigma: a randomized clinical trial

Public title
Effect of weight self-stigma reduction intervention on obesity treatment

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and sign a written consent form
Age between 18 and 50 years
Body mass index (BMI) between 30 and 40 Kg/m2
Confirmation of weight self-stigma by questionnaire
Exclusion criteria:
Suffering from certain diseases or a serious condition (such as bulimia) that affects the results of the study
Receive specialized psychological counseling to treat weight self-stigma in the last 3 months

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be included in the study through availability sampling from the nutrition and diet therapy clinic and will be divided into intervention and control groups using simple randomization and will be matched based on age, BMI, and the use of supplements or drugs. In this study, we will use block randomization. The size of all the blocks is the same and we will have blocks of size 4 in this two-group experiment. For randomization, www.sealedenvelope.com website is used, which can generate random sequences in addition to simple randomization by blocking method. For concealment, we use allocation concealment, which is the method used to execute a random sequence on study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with a random sequence (Sequentially numbered, sealed, opaque envelopes) in which in this method each random sequence is recorded on a card and the cards are placed in the envelopes respectively. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally,

the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Nutrition Faculty, Tabriz University of Medical Sciences

Street address

Nutrition Faculty, Tabriz University of Medical Sciences, Attar Street, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

IR.TBZMED.REC.1402.498

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

2

Description of health condition studied

weight self-stigma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Weight self-stigma score using WBIS questionnaire

Timepoint

assessment of weight self-stigma score at the beginning, day 30, 60 and 120 of the study

Method of measurement

assessment of weight self-stigma score with the Weight Bias Internalization Scale (WBIS) questionnaire

2

Description

adherence percentage to weight loss diet

Timepoint

Measuring percentage of adherence to weight loss diet at the beginning, day 30, 60 and 120 of the study

Method of measurement

Measuring the percentage of adherence to the weight loss diet using the method of Pedro et al. (2009)

Secondary outcomes

1

Description

General mental health

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

GHQ-28 questionnaire

2

Description

the intake of energy, micronutrients and macronutrients

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

FFQ questionnaire and 3-day food record

3

Description

weight

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

With the InBody 230 device

4

Description

height

Timepoint

At the beginning of the study

Method of measurement

seca stadiometer

5

Description

waist circumference

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

tape measure

6

Description

hip circumference

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

tape measure

7

Description

fat mass

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

With the InBody 230 device

8

Description

fat-free mass

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

With the InBody 230 device

9

Description

body water

Timepoint

At the beginning, on the 30th, 60th and 120th day of the study

Method of measurement

With the InBody 230 device

Intervention groups

1

Description

Intervention group: providing a monthly weight-loss diet in the form of a 30% reduction of the total daily caloric requirement calculated by the Mifflin st jeor formula (minimum calorie prescribed diet is 1200 kcal) and with the ratio of macronutrients in the form of 15-18% protein, 50-53% carbohydrates and 30-32% fat, along with the provision of cognitive-behavioral intervention to reduce self-stigma by a psychologist in the form of

weekly group therapy sessions, using PowerPoint, for 12 weeks with CBT technique, providing a summary of the group therapy sessions in the form of a pamphlet at the end of each session and providing the content of the group therapy sessions through a phone call to absentees.

Category

Behavior

2**Description**

Control group: receiving only the weight-loss diet as the same of intervention group

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Keshavarz Nutrition and Diet Therapy Clinic

Full name of responsible person

Dr. Seyed Ali Keshavarz

Street address

No. 3, Fifth Alley, North Kargar St., Tehran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Email

research-vice@tbzmed.ac.ir

Web page address

https://researchvice.tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahdieh Abbasalizad Farhangi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mahdieh Abbasalizad Farhangi

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Mahdieh Abbasalizad Farhangi

Position

Professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available